

# **Analysing business models in the regenerative medicine industry**

Shyketa Daryna Mykolaivna,

Bachelor's degree candidate

ORCHID ID 0009-0008-2991-0071

Scientific supervisor: Nadiia Antypenko, Doctor of Economics, Professor  
Igor Sikorsky Kyiv Polytechnic Institute, Ukraine

*Introduction.* The development of regenerative medicine is becoming an important area of healthcare, providing promising opportunities for mutually beneficial cooperation between patients and healthcare providers. Regenerative therapy, which can be individual or regular, opens up new opportunities for treating both acute and chronic diseases. Differentiating between autologous and allogeneic therapies, regenerative medicine offers selective treatments, restoring health through the regeneration of one's own cells or the use of donor materials.

The main factors that determine the business model for regenerative therapies are the disease area, the availability of starting materials and strategic choices in manufacturing, process control, logistics and regulatory compliance. The stem cell market, which is dynamic, is influenced by clinical trials, the regulatory environment, competition, the adoption of new technologies and financial access.

Integrating regenerative medicine into the healthcare value chain requires a better conceptualisation of the complexity of business models. Considering the concept of a business model as a «heuristic tool» for goal setting can help to develop context-sensitive strategies in policy, regulation and investment. Regenerative medicine's characteristics as an innovative sector in the life sciences pose a double challenge in developing business models and value chains, given the radical innovations and their commercialisation.

Despite the lack of consensus on the theoretical foundations of the business model concept, its value in understanding the logic of the enterprise is recognised. In the field of regenerative medicine, where innovators face the challenges of developing new business models and value chains, the concept is an important tool for achieving profitability and sustainable development in this new innovative sector [1].

*Materials and Methods.* The method of literature search based on databases: Scopus, Web of Science, PubMed; use of the Google Scholar search engine, bibliographic analysis.

*Results and discussion.*

The concept of business models in regenerative medicine.

Using the terms «architecture» and «framework» in the context of defining business models. Terms such as 'architecture' and 'framework' are used to describe a stable framework to which related elements can be attached, organised or given meaning. One method has been to use the concept of «business model architecture» to define the activities associated with the cost structure and the revenue streams of the firm itself. This provides a logical structure for organising the cost and revenue drivers of a business. However, in the radical innovation sector, where products are not yet on the market and there are no revenues, this approach may have limited applicability.

Creating, capturing and delivering value as a key aspect of defining business models. Applying economic value to disruptive innovations can be problematic, as there is considerable inequity in the reimbursement of research and development. For these developments, the business risk can be enormous due to the long gestation time and inequities in reimbursement, which can make it difficult to attract investment. Value, as an element of the conceptual framework, has a significant impact on financing and strategic aspects in healthcare. This is especially true for therapies that require expensive payments in the future and negotiations between healthcare systems over the cost of treatment. The importance of networks and linkages in the context of business models in the field of revolutionary medical innovation (RM). The main idea is that networks and linkages play a critical role in the value creation process of medical innovations, and that successful implementation of these innovations requires interaction and collaboration between different actors and the creation of new networks.

Governance. The discussion of the conceptual framework for value chain management in the context of regulation and innovation in the medical technology industry focuses on business models and different approaches to value chain management depending on the level of regulation and product innovation.

There are 5 types of value chain management structures:

- Market management;
- Modular value chains;
- Relational value chains;
- Value chains;
- Hierarchical value chains.

In the context of regenerative medicine, the authors point out that a relational approach is important, as knowledge in this field is a mixture of codified and tacit knowledge. However, they note that this approach may be difficult for small and medium-sized RM enterprises due to limited financial resources. Thus, they emphasise the need for such enterprises to engage in consultations with others who may have more resources [2, 3].

The study considers certain business models. The materials and services model provides biomaterials, equipment, quality assurance and analytical services. The three main categories of suppliers - starting materials, manufacturing equipment, and regenerative medicine innovators - determine the cost of resources and interact with innovators to share knowledge. The involvement of equipment suppliers indicates the importance of networks and connections, and they are developing specialised equipment in collaboration with innovators. A company is also highlighted that, as an innovator and developer of therapies, aims to generate early revenue by using regenerative medicine to generate data for pharmaceutical companies.

Phase model I/II Early exit (includes firms or organisations that focus on early stage development of RM therapies and exit the RM value chain by selling intellectual property or products without risk. Their strategic goal is to create value by mitigating risk in the early stages of RM therapy development, demonstrating proof of concept, safety and efficacy (Phase I/II clinical trials), and obtaining intellectual property rights for innovative products and processes. The key driver of this business model is the limitation of financial resources - the inability to raise patient capital and the general recognition that RM products will not generate revenue in the short to medium term).

Business model for production and expansion - the business model is key to other business models in the RM value chain, as it is the link between early-stage therapy development actors and subsequent translational activities, including clinical trial planning and clinical acceptance).

Regenerative Medicine Translational Services Business Model - covers firms and organisations that provide specialised advice and guidance on regulatory, clinical trial management, and technology and business management services. The Centre for Gene and Cell Therapy (CGTC) is identified as a key provider of regulatory advisory services, technology and funding, as well as an innovation broker in the RM innovation ecosystem. The study also indicates that public investment in innovation infrastructure may have unintended consequences, such as crowding out less equipped players by more dominant institutions. This underscores the importance of a balanced approach to public investment to ensure that innovation institutions develop and are not crowded out by state institutions.

The virtual business model in translational and regenerative medicine is a strategic choice for small and medium-sized translational medicine companies with limited financial resources. It enables them to focus on developing therapies, paying only for the necessary services and expertise to keep costs down. A fully integrated business model in regenerative medicine is a theoretical component of the previous 5 models. In this case, a company or organisation takes control of all stages from the laboratory to the patient. This implies that the organisation has the ability to bring to the company primarily existing knowledge, which is typical for innovative technologies in the field of regenerative medicine.

In this context, the case of a cell therapy that has received significant market funding indicates that their business model involves the development of stem cells and their transformation into

commercial therapies. This strategy involves participation in all stages of development, from preclinical and clinical trials to market authorisation and clinical implementation. Such a fully integrated business model is ambitious, but can be difficult to implement due to the high financial costs and the need for a wide range of experts and resources [3].

**Conclusions.** The development of regenerative medicine opens up new horizons for modern healthcare. Its significance lies not only in the ability to restore tissues and organs, but also in promoting active interaction between patients and healthcare providers. In regenerative medicine, the concept of business models plays a key role in creating sustainable and efficient systems. This area requires not only research and development, but also successful implementation of the results in practice.

Business models in regenerative medicine must be innovative, responsive to market needs, and promote accessibility and effectiveness of treatment for the sustainable development of this field. The key components of a regenerative medicine business model include suppliers of materials and services, early-stage therapeutic development, manufacturing and expansion, translational services and virtual business models. The interaction between these components determines the successful implementation and commercialisation of regenerative medical technologies.

Despite the promise of these models, it is important to consider the limited financial resources, the complexity of financing, and the need for great effort and resources to succeed.

### **References:**

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